91-10:	as-mm) NOITAЯUD * e40e055S18;GI	PACE 7116 * RCVD AT 11/22/2005 9:19:49 AM [Eastern Standard Time] * SVR:USPTO-EFXRF-6/24 * DNIS:2738300 * CS
Serial No.	10/642,372	PATENT
AM	NDMENTS TO THE	,
1	<u> </u>	ve prosthesis for implantation with a vascular vessel,
2	comprising:	
3	a support fr	me supporting one or more leaflets, wherein each of the
4	one of more leafle	ts has a co-apting edge adjacent an end of the support
5	frame;	
6	the suppor	frame and leafets together functional as a valve to
7	restrict blood flow	in a first direction when implated in the vascular vessel;
8	and	
9	a least one c	entering support element configured to contact a wall of
10	the vessel at a pos	ition distal to the co-apting edge.
	:	
1	2. (Currently Ame	nded) A valve prosthesis for implantation with a vascular
2	vessel, comprising	
3	a plurality o	nded) A valve prosthesis for implantation with a vascular flegs, each comprising a leaflet having an inner edge and a support frame carrying the outer edge of the plurality of legs are interconnected such that the support erpentine configuration in which the outer edges of the
4	and an outer edge	and a support frame carrying the outer edge of the
5	leaflet;	
6	wherein the	plurality of legs are interconnected such that the support
7	frame includes a s	
8	leaflets exert radia	force against the walls of vascular vessel and generally tours thereof;
9	conform to the co	
10	wherein the	inner edges of the plurality of leaflets traverse the vessel
11	lumen such that th	plurality of leaflets are cooperable to define an opening
12	therebetween to	permit fluid flow in a first direction along the vascular
13	vessel, while eng	aging each other sufficiently to restrict fluid flow in a
14	second direction	pposing the first direction; and
15	wherein the	valve prosthesis further comprises a second frame
16	portion attached to	least one the plurality of legs and extending <u>at least</u> one
17	of distally and pro	ximally therefrom.
		·
	·	-2-
		· · · · ·

9 <b>1-1</b> 0:(	PACE 8/16 * RCVD AT 11/22/2005 9:19:49 AM [Eastern Standard Time] * SVR:USPTO-EFXRF-6/24 * DNIS:2738300 * CSID:8123309049 * DURATION (mm-ss
Serial No.	10/642,372 PATENT
1	3. (Original) A valve prosthesis for implantation with a vascular vessel,
2	comprising:
3	a serpentine shaped frame having a first pair of bends and a second
4	pair of bends, a first pair bends being oriented at a first end of the
5	serpentine-shaped frame and located approximately 180° degrees with
6	respect to one another, the second pair of bends being oriented at the
7	second end of the serpentine-shaped frame and located approximately
8	180° degrees with respect to one another and approximately 90° with
9	respect to the first pair of bends, wherein the first pair of bends and a first
10	bend of the second pair of bends comprise a first leg of the implantable
11	valve, and the first pair of bends and a second bend of the second pair of
12	bends comprise a second leg of the implantable valve, each of the first and
13	second legs having a covering extending thereover, wherein the first and
14	second legs define a opening therebetween that opens and closes in
15	response to bidirectional fluid flow.
1	4. (Original) The Walve prosthesis of claim3, wherein the frame includes
2	at least one open section therealong, the at least one open section
3	including a circumferential member partially encircling the frame, thereby
4	providing a bridge across the at least one open section.
1	5. (Original) The valve prosthesis of claim 3, wherein the the frame
2	includes at least one circumferential member attached to the adjacent pair
3	bends of the first and second legs the frame such that the circumferential
4	member is interposed between the legs and the walls of the vascular vessel
5	to a least limit contact therebetween.
1	6. (Original) The walve prosthesis of claim 3, wherein the covering
2	comprises a biomaterial.
	-3-
	[

91-10:(	ee-mm) NOITAAUD * e10e088818:Gi	: 19:49 AM [Eastern Standard Time] * SVR:USPTO-EFXRF-6124 * DNIS:2738300 * CS	PACE 9116 * RCVD AT 11/22/2005 9
Serial No.	10/642,372	:	PATENT
1		valve prosthesis of claim 6, wherein the bioma	erial
2	includes an extra	ellular collagen matrix.	
1	· .	ve prosthesis for implantation within a vascula	r vessel,
2	comprising:		
3	1	ame supporting two or more leaflets, the two	or more
4	- I	a co-aptation position;	
5		frame and leaflets together functional as a val	i
6		in a first direction when implanted in the vascula	l i
7	i	frame comprising frame elements to which the	l l
8		rame elements non-circumferentially contacting	
9	j	sel such that the frame elements are non-centeri	hg of the
10	co-aptation positi	[]	
11	at least one	centering support element configured to cente	r the co-
12	aptation position		
1		valve prosthesis, wherein the at least one cente	_
2		extends laterally from the support frame such the	
3	interposed betwe	en at least one of the two or more leaflets and t	he walls
4	of the vessel.		
1	10. (Original) A	alve prosthesis for implantation within a vascul	ar vessel,
2	comprising:		
3	1	ame supporting one or more leaflets;	
4	1	formed with a remodellable material configu	
5	contact wall of the	vascular vessel in a predetermined orientation	) <b>;</b>
6	ļ .	e centering support element for facilitating co	
7	between the wall	and the material in the predetermined orientati	on.
			_
1	· -	alve prosthesis for implantation within a vascul	ar vessel,
2	comprising:		
		-4-	
		:	

91-10:(5	e-mm) NOITARUG * e40e088518;GIƏD	PAGE 10/16 * RCVD AT 11/22/2005 9:19:49 MA [Eastern Standard Time] * SVR:USPTO-EFXRF-6/24 * DNIS:27/38/300 *
	1	PATENT
Seriai No.	10/642,372	
3	a valve stru	ture having a first end and a second end, a plurality of
4	I I I	an outer edge and an inner edge, the plurality of inner
5		prifice therebetween for allowing the passage of fluid in
6		pe plurality of leaflets configured to co-apt with one
7	l ii	the passage of fluid in a second, opposite direction;
8	1	me that generally co-extends along the outer edges of
9	the plurality of lea	ilets; and
10	a centering	support structure comprising one or more centering
11	1	g from the valve structure that engage the walls of the
12	vascular vessel in	a manner to facilitate centering of the orifice within the
13	lumen of the vasc	lar vessel during deployment of the valve prosthesis.
1	12. (Original) The	valve prosthesis of claim 11, wherein the one or more
2	centering element	extend from at least one of the first end and the second
3	end of the valve st	ructure
1	13. (Original) The	valve prosthesis of claim 11, wherein the one or more
2	centering element	s comprise a second frame portion attached to the first
3	end of valve struct	re and extending longitudinally therefrom such that the
4	second frame por	on is deployed prior to the valve structure
1	14. (Original) The	valve prosthesis of claim 11, wherein the one or more
2	centering elemen	s comprise a second frame portion attached to the
3	second end of val	e structure and extending longitudinally therefrom such
4	that the second fr	me portion is deployed after the valve structure.
1	15. (Original) The	valve prosthesis of claim 11, wherein the one or more
2	centering element	s comprise a second frame portion attached to the first
3	end of the valve st	ructure and a third frame portion attached to the second
4	end of the valve	ructure, both extending longitudinally from the valve
5	structure.	
		-5-
	ĺ	

9 <b>1-7</b> 0:(s	es-mm) NOITARUG * 64060EES18:012	PAGE 11/16 * RCVD AT 11/22/2005 9:19:49 AM [Eastern Standard Time] * SVR:USPTO-EFXRF-6/24 * DNIS:2738300 * C
Serial No.	10/642,372	PATENT
1	16. (Original) The	valve prosthesis of claim 11, wherein the centering
2	support structure	ncludes centering support elements extending aterally
3	from the support	rame to contact the walls of the bodily passage, the
4	lateral centering s	pport elements being interposed between the plurality
5	of leaflets and the	walls of the vascular vessel.
1	17. (Original) The	valve prosthesis of claim 11, wherein the plurality of
2	leaflets comprise	remodelable extracellular collagen matrix.
•		
1	18. (Original) The	valve prosthesis of claim 11, wherein the plurality of
2	leaflet consists of	two leaflets.
1	19. (Original) The	valve prosthesis of claim 11, wherein the plurality of
2	leaflet consists of	three leaflets.
1	20. (Original) A v	eve prosthesis for implantation within a vascular vessel,
2	comprising:	
3	a valve str	cture including a plurality of legs, one or more of the
4	plurality of legs of	mprising a leaflet having an inner edge and an outer
5	edge, and a supp	ort frame carrying outer edge, such that the outer edge
6	directly contacts t	ne wall of the bodily passage when deployed the rein; and
7	a centering	support structure comprising one or more centering
8	1	to the legs of the valve structure, the one or more
9		s configured to contact the walls of the vessel at points
10	extending at least	one of proximal, distal, and lateral to the outer edge.
1	1 !!	valve prosthesis of claim 20, wherein the centering
2	elements span ad	acent ones of the plurality of legs of the valve structure.
	[	
		::
		<b>-6</b> -

91-40:(s	- e+09023309049 * DURATION (mm.	SE 12/16 * RCVD AT 11/22/2005 9:19:49 AM [Eastern Standard Time] * SVR:USPTO-EFXRF-6/24 * DNIS:27/38300 *	)Aq
Serial No.	10/642,372	PATENT	
1	22. (Original) The	valve prosthesis of claim 20, wherein the centering	
2	elements extend	terally from the plurality of legs of the valve structure.	
1	23. (Original) A va	ve prosthesis for implantation within a vascular vessel,	
2	comprising:		
3	a valve stru	cture including a plurality of legs, one or more of the	
4	plurality of legs d	mprising a leaflet having an inner edge and an outer	
5	edge, and a suppo	frame carrying the outer edge such that the outer edge	
6	directly contacts to	e wall of the vascular vessel when deployed therein;	
7	wherein the	support frame comprises a plurality of interconnected	
8	serpentine rows e	ch having at least eight bends and eight struts; and	
9	wherein the	plurality of leaflets are attached to the support structure	
10	such that each s	pans at least two adjacent ones of the plurality of	
11	serpentine rows,	and such that the at least eight struts of each of the at	
12	least two adjacent	rows include both struts generally covered by a portion	
13	of the outer edge	nd struts that remain uncovered by the leaflet material,	
14	the uncovered str	ts comprise centering support elements configured to	
15	provide additiona	longitudinal support to the valve prosthesis.	
1	24. (Original) T	e valve prosthesis of claim 23, wherein:	
2	the pluralit	of interconnected serpentine rows comprise two	
3	adjacent rows def	ining a row of closed cells.	
1	25. (Original) The	valve prosthesis of claim 23, wherein the plurality of	
2	leaflets span at le	st three serpentine rows of the support structure.	
1	26. (Original) The	valve prosthesis of claim 23, wherein the plurality of	
2	interconnected se	pentine rows are formed from a single nitinol tube.	
		· ·	
1	27. (Original) A v	alve prosthesis for implantation within a vascular vessel,	
2	comprising:		
		-7-	
	i li	, I I	

91-10:(s	e-mm) NOITARUG * 040068518:GIB:	# PAGE 13/16 * RCVD AT 11/22/2005 9:19:49 AM [Eastern Standard Time] * SVR:USPTO-EFXRF-6/24 * DNIS:2738300 * (
Serial No.	10/642,372	PATENT
3	two or more	eaflets having a resilient outer edge and an inner edge,
4	the plurality of re	silient outer edges collectively exerting radial force
5	against the walls	of the vascular vessel, the plurality of inner edges
6	configured to defin	e an orifice to allow passage of blood flowing toward the
7	heart and coapt w	th one another to restrict blood flowing in a direction
8	opposite thereto;	nd
9	a plurality o	struts extending from at least one resilient outer edge
10	to contact the wall	of the vascular vessel to facilitate the centering of the
11	orifice within the	vascular vessel during deployment of the valve
12	prosthesis.	
1	28. (Original) The	valve prosthesis of claim 27, wherein:
2	the two or h	ore leaflets comprise a remodelable material.
		. [
. 1	29. (Original) A v	ve prosthesis for implantation within a vascular vessel,
2	comprising:	
3	one or more	leaflets having a resilient outer edge adapted to exert
4	force against the	alls of the vascular vessel; and
5	! 11	ntering support elements that extend laterally from the
6	one or more lea	flets to contact the walls of the vessel to provide
7	longitudinal cente	ing support to the valve prosthesis.
1	30. (Original) A v	ve prosthesis for implantation within a vascular vessel,
2	comprising:	
3	a self-expa	ding support frame which in a relaxed condition has
4	leaflet-supporting	frame elements extending transverse to a longitudinal
5	axis of the suppor	.
6	the leaflet-suppor	ng frame elements supporting one or more leaflets, the
7	one or more leafl	ts also extending transverse to a longitudinal axis of the
8	support frame in	e relaxed condition and each presenting an outwardly-
9	facing leaflet surfa	ce; and
		-8-
	1	

9 <b>1-1</b> 0:(s	Semm) NOITARUD * DURATION (mm.	PAGE 14/16 * RCVD AT 11/22/2005 9:19:49 AM [Eastern Standard Time] * SVR:USPTO-EFXRF-6/24 * DNIS:2738300 *
Serial No.	10/642,372	PATENT
10	the support	frame also including at least one frame element
11	occurring outward	of the outwardly-facing leaflet surface and longitudinally
12	1	t least a portion of the surface.
1	31. (Currently Ame	ended) The valve prosthesis of claim $\times 30$ , wherein the
2	one or more leafle	s comprise a remodelable material.
1	32. (Original) A va	ve prosthesis for implantation within a vascular vessel,
2	comprising:	
3	a support fr	me having a first end and supporting one or more valve
4	leaflets;	
5	the support	frame having a plurality of frame elements terminating
6	at said first end an	configured to contact the wall of the vascular vessel at
7	a plurality of discre	te positions thereby creating pivot points rendering the
8	support frame non	self-centering; and
9	at least one	entering support element attached to the support frame
10	for contacting the	essel wall at a position longitudinally spaced from the
11	pivot points and re	ducing pivotal freedom of the support frame about the
12	pivot points.	
1	33. (Original) The	valve prosthesis of claim 32, wherein the centering
2	support elements	are proximal to pivot points.
1	34. (Original) The	valve prosthesis of claim 32, wherein the centering
2	support elements	are distal to pivot points.
1	35. (Original) The	valve prosthesis of claim 32, wherein the centering
2	support element a	re co-extensive with support frame.
1	36. (Original) A	ve prosthesis for implantation within a vascular vessel,
2	comprising:	
		-9-

91-10:(5	PAGE 15/16 * RCVD AT 11/22/2005 9:19:49 AM [Eastern Standard Time] * SVR:USPTO-EFXRF-6/24 * DNIS:2738300 * CSID:8123309049 * DURATION (mm-
Serial No.	10/642,372 PATENT
3	a support frame having a first end and supporting one or more valve
4	leaflets; and
5	at least one centering support element attached to the support frame,
6	the centering support element comprising two elongate portions
7	converging toward one another and connected through an adjoining
8	portion adapted for contact with the vessel.
_	
1	37. (Original) A valve prosthesis for implantation in a body vessel,
2	comprising:
3	first and second self-expandable frames, the first self-expandable
<b>4</b> 5	frame axially spaced from the second self-expandable frame; a connecting strut connecting the first and second self-expandable
6	frames; and
7	a valve leaflet attached to the first self-expandable frame and
8	moveable between a first position that permits fluid flow through the body
9	vessel in a first direction and a second position that substantially prevents
10	fluid flow through the body vessel in a second, opposite direction.
1	38. (Currently Amended) The valve prosthesis of claim × 37, wherein the
2	valve leaflet is attached to the connecting strut.
1	39. (Original) The valve prosthesis of claim 37, wherein the second self-
2	expandable frame contacts an inner wall of the body vessel when in an
3	expanded configuration.
	f. e
:	
	- 10 -

## This Page is Inserted by IFW Indexing and Scanning Operations and is not part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

BLACK BORDERS

IMAGE CUT OFF AT TOP, BOTTOM OR SIDES

FADED TEXT OR DRAWING

BLURRED OR ILLEGIBLE TEXT OR DRAWING

SKEWED/SLANTED IMAGES

COLOR OR BLACK AND WHITE PHOTOGRAPHS

GRAY SCALE DOCUMENTS

LINES OR MARKS ON ORIGINAL DOCUMENT

REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY

## IMAGES ARE BEST AVAILABLE COPY.

OTHER:

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.